REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the present application are respectfully requested in view of the amendments to the claims and remarks presented herewith, which place the application into condition for allowance.

Status of the Claims and Formal Matters

Claims 1-137 are currently pending in this applications. Of these, Claims 40-137 have been withdrawn from further consideration as allegedly being drawn to non-elected subject-matter. Applicants hereby assert the right to reclaim cancelled or withdrawn subject-matter in co-pending applications. By this paper, Claim 28 has been amended, without prejudice. No new matter has been introduced by this amendment. Support for the amended recitations can be found throughout the specification.

The amendments as presented herein are not made for purposes of patentability within the meaning of §§101, 102, 103, or 112. Rather, these amendments are made for clarity and to round out the scope of protection to which Applicants are entitled.

Claims 28-36 were objected to under 37 C.F.R. §1.75(c) as allegedly being in improper form because multiple dependent Claim 28 depends on multiple dependent claim 27, and claims 29-36 directly or indirectly depend on Claim 28. By this paper, Claim 28 has been amended, thereby obviating this objection. Reconsideration and withdrawal of the objections to Claims 28-36 are respectfully requested.

Rejections under 35 U.S.C. §102(b)

Claims 1-28 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Stowell et al (J. Med. Chem. (1995) 38: 1411-1413; hereinafter "Stowell"). According to the Office Action, Stowell discloses suberanilohydroxamic acid, which was prepared as a white solid free of impurities (at page 1413, col. 1, lines 19-21 as set forth in the Office Action). The Examiner states that the compound disclosed by Stowell has a melting point of 159-160.5, which is allegedly close to the melting point range extracted from the DSC thermogram presented in the instant specification. The Office Action contends that Stowell compound differs from the claimed subject matter in that the reference is silent as to crystalline form, but that Applicants must show that their crystalline form is different from the one prepared by Stowell. Applicants

respectfully traverse this rejection.

Stowell describes the synthesis of *N*-hydroxy-*N'*-phenyloctanediamide (suberanilohydroxamic acid) from the methyl ester of suberanilic acid. The resulting product was synthesized as a white solid at 90% yield and has a melting point of 159-160.5°C. Stowell is silent as to whether the compound is in crystalline form. Consequently, Stowell does not perform any assays to test whether the compound is in crystal form, such as X-ray diffraction (XRD) analysis and differential scanning calorimetry (DSC). Stowell's compound is analyzed only by thin-layer chromatography and nuclear magnetic resonance to detect the presence of any impurities. Therefore, it is difficult to determine from the reference whether Stowell's compound would have the same or substantially similar X-ray diffraction pattern as the crystalline form of SAHA as shown in instant Figure 13A.

However, Applicants respectfully direct the Examiner to Example 5 of the instant specification, which provide comparative XRD analyses of the instant SAHA Form I and various prior art reference samples of SAHA, including a compound synthesized according to the method of Stowell. See, for example, Table 6, "Reference 4" and compare Table 7 (the instant SAHA Form I) and Table 11 (SAHA Reference Sample 4). The XRD analyses clearly reveal that the instant SAHA Form I has a different diffraction pattern than SAHA Reference Sample 4 (Stowell's compound). Furthermore, a comparison of instant Figures 13A and 13E, corresponding to instant SAHA Form I and Stowell's compound respectively, demonstrates the differences in peaks obtained by XRD analysis in graphical form.

Example 7 describes comparative DSC analyses of instant SAHA Form I and the various prior art reference samples described in Example 5. Reference Sample 4, otherwise referred to herein as Stowell's compound, shows a marked difference in the DSC peaks at the onset temperature and the peak temperature (see Table 13) as compared to instant SAHA Form I. Additionally, a comparison of Figure 14A (instant SAHA Form I) and Figure 14E (Stowell's compound) clearly show differences between the two forms of SAHA.

Applicants respectfully submit that Stowell fails to anticipate the instant invention because Stowell does not teach or disclose a crystal form of SAHA that has an X-ray diffraction pattern or Differential Scanning Calorimetry thermogram that is the same or substantially similar to the instantly claimed SAHA Form I. Stated otherwise, Stowell teaches a SAHA polymorph that is clearly different from instant SAHA Form I. Under §102, a claim is anticipated only if

each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Reconsideration and withdrawal of the rejection under §102(b) are respectfully requested.

Rejections under 35 U.S.C. §103(a)

Claims 29-39 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Stowell in view of Kabadi (EP 0 547 000; hereinafter "Kabadi"). According to the Office Action, Stowell allegedly teaches a solid form of SAHA, a pharmaceutical composition comprising SAHA, and its pharmacological potential as an agent for the treatment of cancer. Stowell, however, fails to teach the compositions claimed in instant claims 29-39. Kabadi allegedly teaches a pharmaceutical composition for oral administration comprising fluvastatin as active ingredient, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The Office Action contends that microcrystalline cellulose, croscarmellose sodium, and magnesium stearate are commonly used additives in oral pharmaceutical compositions, and are well-known to the skilled artisan. One of ordinary skill in the art would allegedly find it obvious to use the combination of physiologically inactive ingredients taught by Kabadi in a pharmaceutical composition for oral administration of SAHA. The Office Action further argues that the skilled artisan would also be able to determine through routine experimentation the amount of the active ingredient SAHA to be administered to a patient. Finally, the Office Action states that Claims 29-36 do not require the secondary reference (Kabadi) and alleges that making capsules or dissolving/suspending a compound for intravenous administration or other modes of administering a compound is common in the art. This rejection is respectfully traversed.

As discussed above, Stowell does not teach or suggest a crystalline form of SAHA that is the same or substantially similar to instantly claimed SAHA Form I. The present inventors have demonstrated in Examples 5 and 7 that Stowell's compound clearly has a different XRD pattern as seen in instant Figure 13E that differs from instant SAHA Form I (see Figure 13A) and has a different DSC thermogram as shown in instant Figure 14E, which is distinct from the DSC thermogram of instant SAHA Form I shown in Figure 14A. The compound described by Stowell appears to be a different polymorph of SAHA that exhibits different physical properties from instant SAHA Form I.

Kabadi does not cure the defects of Stowell. Kabadi relates to a stabilized pharmaceutical composition containing fluvastatin (an HMG-CoA reducatase inhibitor), microcrystalline cellulose, a disintegrant (such as croscarmellose sodium), and a lubricant (like magnesium stearate). Kabadi does not teach, suggest, or disclose SAHA.

To establish a *prima facie* case of obviousness under §103(a), three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. MPEP §2143. Applicants respectfully submit that Stowell and Kabadi, whether considered separately or in combination with each other, fail to teach or suggest all of the instant claim limitations. Because Stowell and Kabadi do not teach a SAHA that is characterized by an XRD pattern or a DSC thermogram substantially similar to instant SAHA Form I, reconsideration and withdrawal of the rejection under §103(a) is respectfully requested.

Double Patenting

Claims 28, 29, 31, 32, 37, 38, and 39 were provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 156-159 of co-pending Application No. 10/379,149. According to the Office Action, this is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The question of whether there is indeed double patenting between the claims of the instant application and co-pending Application No. 10/600,132 depend on whether the instant claims are found by the Office to be patentable. MPEP §804(I)(B). Once the provisional rejection has been made, there is nothing the Examiner and the Applicant must do until the other application issues. *In re Mott* 539 F.2d 1291, 1296 (1976). Consequently, Applicants respectfully request that cancellation or amendment of the conflicting claims such that they are no longer coextensive in scope be held in abeyance until it is the final impediment preventing the present application from proceeding to allowance.

CONCLUSION

Favorable action on the merits is respectfully requested. If any discussion regarding this Response is desired, the Examiner is respectfully urged to contact the undersigned at the number given below, and is assured of full cooperation in progressing the application to allowance.

Respectfully submitted,

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